AO 120 (Rev. 3/04)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court TRENTON on the following ☑ Patents or ☐ Trademarks:

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
07-5367	11/8/2007	TRENTON

PLAINTIFF	DEFENDANT
CELGENE CORPORATION NOVARTIS PHARMACEUTICALS CORPORATION NOVARTIS PHARMA AG	ACTAVIS SOUTH ATLANTIC LLC ABRIKA PHARMACEUTICALS, INC.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	5,908,850		SEE ATTACHED COMPLAINT
2	6,355,656		
3	6,528,530		
4	5,837,284		
5	6,635,284		

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
WILLIAM T. WALSH, CLERK		11/9/2007

Copy 1—Upon initiation of action, mail this copy to Director **Copy 3—Upon termination of action, mail this copy to Director**
Copy 2—Upon filing document adding patent(s), mail this copy to Director **Copy 4—Case file copy**

41. Actavis's submission of ANDA No. 79-108 to the FDA, including its Paragraph IV Certification, to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Actavis's Proposed Products prior to the expiration of the 1998 '284 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

42. Unless enjoined by this Court, Actavis, upon FDA approval of ANDA No. 79-108, will infringe the 1998 '284 patent under 35 U.S.C. § 271 by making, using, offering to sell, selling, or importing into the United States Actavis's Proposed Products.

43. Actavis had notice of the 1998 '284 patent prior to undertaking its act of infringement. Actavis's infringement of the 1998 '284 patent has been, and continues to be, willful and deliberate.

44. Plaintiffs will be substantially and irreparably damaged and harmed if Actavis's infringement of the 1998 '284 patent is not enjoined. Plaintiffs do not have an adequate remedy at law for this infringement.

Count V: Actavis's Filing of the ANDA Infringes the 2003 '284 Patent.

45. Plaintiffs repeat and reallege the allegations of paragraphs 1-24 as though fully set forth herein.

46. Actavis's submission of ANDA No. 79-108 to the FDA, including its Paragraph IV Certification, to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Actavis's Proposed Products prior to the expiration of the 2003 '284 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

47. Unless enjoined by this Court, Actavis, upon FDA approval of ANDA No. 79-108, will infringe the 2003 '284 patent under 35 U.S.C. § 271 by making, using, offering to sell, selling, or importing into the United States Actavis's Proposed Products.

48. Actavis had notice of the 2003 '284 patent prior to undertaking its act of infringement. Actavis's infringement of the 2003 '284 patent has been, and continues to be, willful and deliberate.

49. Plaintiffs will be substantially and irreparably damaged and harmed if Actavis's infringement of the 2003 '284 patent is not enjoined. Plaintiffs do not have an adequate remedy at law for this infringement.

Prayer For Relief

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A Judgment that Actavis has infringed one or more claims of the '850 patent;

(B) A Judgment that Actavis has infringed one or more claims of the '656 patent;

(C) A Judgment that Actavis has infringed one or more claims of the '530 patent;

(D) A Judgment that Actavis has infringed one or more claims of the 1998 '284 patent;

(E) A Judgment that Actavis has infringed one or more claims of the 2003 '284 patent;

(F) An Order that the effective date of any FDA approval of ANDA No. 79-108 be a date which is not earlier than the later of the expiration of the '850 patent, or any expiration of exclusivity to which Plaintiffs are or become entitled;

(G) An Order that the effective date of any FDA approval of ANDA No. 79-108 be a date which is not earlier than the later of the expiration of the '656 patent, or any expiration of exclusivity to which Plaintiffs are or become entitled;

(H) An Order that the effective date of any FDA approval of ANDA No. 79-108 be a date which is not earlier than the later of the expiration of the '530 patent, or any expiration of exclusivity to which Plaintiffs are or become entitled;

(I) An Order that the effective date of any FDA approval of ANDA No. 79-108 be a date which is not earlier than the later of the expiration of the 1998 '284 patent, or any expiration of exclusivity to which Plaintiffs are or become entitled;

(J) An Order that the effective date of any FDA approval of ANDA No. 79-108 be a date which is not earlier than the later of the expiration of the 2003 '284 patent, or any expiration of exclusivity to which Plaintiffs are or become entitled;

(K) Preliminary and permanent injunctions enjoining Actavis and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing into the United States Actavis's Proposed Products until after the expiration of the '850 patent;

(L) Preliminary and permanent injunctions enjoining Actavis and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing into the United States Actavis's Proposed Products until after the expiration of the '656 patent;

(M) Preliminary and permanent injunctions enjoining Actavis and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing into the United States Actavis's Proposed Products until after the expiration of the '530 patent;

(N) Preliminary and permanent injunctions enjoining Actavis and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using,

offering to sell, selling, or importing into the United States Actavis's Proposed Products until after the expiration of the 1998 '284 patent;

(O) Preliminary and permanent injunctions enjoining Actavis and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing into the United States Actavis's Proposed Products until after the expiration of the 2003 '284 patent;

(P) A declaration that the commercial manufacture, use, offer to sell, sale, or importation into the United States of Actavis's Proposed Products will directly infringe or induce and/or contribute to infringement of the '850 patent;

(Q) A declaration that the commercial manufacture, use, offer to sell, sale, or importation into the United States of Actavis's Proposed Products will directly infringe or induce and/or contribute to infringement of the '656 patent;

(R) A declaration that the commercial manufacture, use, offer to sell, sale, or importation into the United States of Actavis's Proposed Products will directly infringe or induce and/or contribute to infringement of the '530 patent;

(S) A declaration that the commercial manufacture, use, offer to sell, sale, or importation into the United States of Actavis's Proposed Products will directly infringe or induce and/or contribute to infringement of the 1998 '284 patent;

(T) A declaration that the commercial manufacture, use, offer to sell, sale, or importation into the United States of Actavis's Proposed Products will directly infringe or induce and/or contribute to infringement of the 2003 '284 patent;

(U) If Actavis engages in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Actavis's Proposed Products prior to the expiration of the

'850 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(V) If Actavis engages in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Actavis's Proposed Products prior to the expiration of the '656 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(W) If Actavis engages in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Actavis's Proposed Products prior to the expiration of the '530 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(X) If Actavis engages in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Actavis's Proposed Products prior to the expiration of the 1998 '284 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(Y) If Actavis engages in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Actavis's Proposed Products prior to the expiration of the 2003 '284 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(Z) A Judgment that Defendants' acts of infringement with respect to the methods or compositions claimed in the Patents-in-Suit are willful and deliberate.

(AA) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § § 271(e)(4) and 285, entitling Plaintiffs to their reasonable attorney fees;

(BB) Costs and expenses in this action; and

(CC) Such further and other relief as this Court may deem just and proper.

Dated: November 8, 2007

Respectfully submitted,

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LOCAL CIVIL RULE 11.2 & 40.1 CERTIFICATION

I hereby certify that the matters captioned: (1) *Celgene Corporation, et al. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 04-4030 (FLW)(JJH); (2) *Celgene Corporation, et al. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 06-6154 (FLW)(JJH); (3) *Celgene Corporation, et al. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 07-4459 (FLW)(TJB); and (4) *Celgene Corporation, et al. v. IntelliPharmaCeutics, Corp.*, Civil Action No. 07-4854 (FLW)(JJH), all pending before the Honorable Freda L. Wolfson, are related to the matter in controversy because they involve the same plaintiffs and patents, and involve proposed generic versions of FOCALIN® and FOCALIN XR® drug products.

I also certify that the matters captioned *Celgene Corporation, et al. v. Abrika Pharmaceuticals, Inc., et al.*, Civil Action No. 06-5818 (SDW)(MCA), *Celgene Corporation, et al. v. KV Pharmaceuticals Company*, Civil Action No. 07-4819 (SDW)(MCA), and *Celgene Corporation, et al. v. Barr Laboratories, Inc., et al.*, Civil Action No. 07-5256 (SDW)(MCA) are related cases.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: November 8, 2007

Respectfully submitted,

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS PHARMA AG,	**Civil Action No.** 07-5367(ELW)
Plaintiffs,	**COMPLAINT FOR PATENT INFRINGEMENT**
v.	
ACTAVIS SOUTH ATLANTIC LLC and ABRIKA PHARMACEUTICALS, INC.,	**(Filed Electronically)**
Defendants.	

Plaintiffs Celgene Corporation ("Celgene") and Novartis Pharmaceuticals Corporation and Novartis Pharma AG (together, "Novartis"), by their attorneys, for their Complaint against Defendants Actavis South Atlantic LLC and Abrika Pharmaceuticals, Inc. allege as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 United States Code, arising from Defendants' filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Novartis' patented FOCALIN XR® drug product prior to the expiration of Celgene's United States Patent Nos. 5,908,850 (the "'850 patent"), 6,355,656 (the "'656 patent"), 6,528,530 (the "'530 patent"), 5,837,284 (the "1998 '284 patent"), and 6,635,284 (the "2003 '284 patent"), all of which cover the FOCALIN XR® product or its use.

The Parties

2. Plaintiff Celgene Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

3. Plaintiff Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

4. Plaintiff Novartis Pharma AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

5. Defendant Abrika Pharmaceuticals, Inc. was a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 13800 N.W. 2nd Street, Suite 190, Sunrise, Florida 33325. Upon information and belief, on May 17, 2007, it was converted from a Delaware Corporation to a Delaware limited liability company pursuant to Section 18-214 of the Limited Liability Company Act. Subsequent to that event, Abrika

Pharmaceuticals, Inc. changed its name to Actavis South Atlantic LLC. Abrika Pharmaceuticals, Inc. continues to maintain a website at http://www.abrika.com.

6. Defendant Actavis South Atlantic LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 13800 N.W. 2nd Street, Suite 190, Sunrise, Florida 33325.

7. Actavis South Atlantic LLC and Abrika Pharmaceuticals, Inc. are collectively referred to herein as "Actavis."

8. Upon information and belief, Actavis is in the business of manufacturing, distributing, and selling generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

Jurisdiction and Venue

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over Actavis by virtue of, *inter alia*, i) its continuous and systematic contacts with New Jersey (*e.g.*, upon information and belief, Actavis directly, or through its divisions, subsidiaries, agents and/or alter-egos, manufactures, distributes, markets and sells generic pharmaceutical products in this judicial district); and ii) The Honorable Susan D. Wigenton's May 17, 2007 Order in the matter captioned *Celgene Corporation, et al. v. Abrika Pharmaceuticals, Inc., et al.*, Civil Action No. 06-5818 (SDW)(MCA), finding that Actavis is subject to personal jurisdiction in the State of New Jersey. Further, upon information and belief, Actavis directly, or through its divisions, subsidiaries, parents, agents and/or alter-egos maintains executive offices and a manufacturing facility in this judicial district.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patents-in-Suit and the FOCALIN XR® Drug Product

12. The '850 patent, entitled "Method of Treating Attention Deficit Disorders With D-Threo Methylphenidate," duly and legally issued to Celgene on June 1, 1999, by the United States Patent and Trademark Office ("PTO"). A copy of the '850 patent is attached hereto as Exhibit A. The '850 patent includes claims directed to methods of treatment using *d-threo* methylphenidate.

13. The '656 patent, entitled "Phenidate Drug Formulations Having Diminished Abuse Potential," originally duly and legally issued to Celgene on March 12, 2002, by the PTO. An *Ex Parte* Reexamination Certificate, which amended certain claims of the '656 patent and added new claims, issued on March 27, 2007, by the PTO. Copies of the '656 patent and the *Ex Parte* Reexamination Certificate for the '656 patent are attached hereto as Exhibit B. The '656 patent claims are directed to, *e.g.*, pharmaceutical unit dosages of *d-threo* methylphenidate.

14. The '530 patent, entitled "Phenidate Drug Formulations Having Diminished Abuse Potential," duly and legally issued to Celgene on March 4, 2003, by the PTO. A copy of the '530 patent is attached hereto as Exhibit C. The '530 patent claims are directed to pharmaceutical unit dosages that include pharmaceutical compositions of *d-threo* methylphenidate.

15. The 1998 '284 patent, entitled "Delivery of Multiple Doses of Medications," duly and legally issued to Celgene on November 17, 1998, by the PTO. A copy of the 1998 '284 patent is attached hereto as Exhibit D. The 1998 '284 patent includes claims directed to extended release dosage forms of methylphenidate drug products.

16. The 2003 '284 patent, entitled "Delivery of Multiple Doses of Medications," duly and legally issued to Celgene on October 21, 2003, by the PTO. A copy of the 2003 '284 patent is attached hereto as Exhibit E. The 2003 '284 patent includes claims directed to an extended

release dosage form and claims directed to a method of treating disease with certain extended release dosage forms.

17. Celgene is the owner by assignment of all right, title and interest in the '850 patent, the '656 patent, the '530 patent, the 1998 '284 patent, and the 2003 '284 patent (collectively referred to herein as the "Patents-in-Suit"). Novartis Pharma AG is the exclusive licensee, in certain fields of use, of the Patents-in-Suit.

18. Novartis Pharmaceuticals Corporation holds an approved New Drug Application for extended release capsules of 5 mg, 10 mg, 15 mg, and 20 mg, extended release capsules of the hydrochloride salt of *d-threo*-methylphenidate, also known as dexmethylphenidate hydrochloride, which it sells as commercial products under the trade name FOCALIN XR®. These commercial products or their use are covered by one or more claims of the Patents-in-Suit.

Acts Giving Rise To This Action

19. Actavis prepared and filed with the FDA, pursuant to 21 U.S.C. § 355(j), ANDA No. 79-108 to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of extended release dexmethylphenidate hydrochloride capsules 5 mg, 10 mg, 15 mg, and 20 mg (these generic capsules are collectively referred to herein as "Actavis's Proposed Products") prior to the expiration of the Patents-in-Suit.

20. In connection with the filing of its ANDA as described in the preceding paragraph, Actavis provided written certification to the FDA, as called for by 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"), alleging that the claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the activities described in Actavis's ANDA.

21. By letter dated September 26, 2007, Actavis notified Celgene and Novartis ("the Notification Letter"), that it had filed with the FDA ANDA No. 79-108, including its Paragraph

IV Certification, to obtain FDA approval to engage in the commercial manufacture, use, offer to sell, sale, or importation into the United States of extended release dexmethylphenidate hydrochloride capsules 5 mg, 10 mg, 15 mg, and 20 mg.

22. Upon information and belief, if ANDA No. 79-108 is approved, it is the intention of Actavis to commercially manufacture, use, and sell Actavis's Proposed Products in the United States.

23. Upon information and belief, Actavis's ANDA No. 79-108 contains information showing that Actavis's Proposed Products (a) are bioequivalent to the patented FOCALIN XR® products; (b) have the same active ingredient as the patented FOCALIN XR® products; (c) have the same route of administration and strength as the patented FOCALIN XR® products; and (d) have the same, or substantially the same, dosage form and proposed labeling, and the same indication and usage, as the patented FOCALIN XR® products.

24. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) before the expiration of forty-five days from the date of receipt by Plaintiffs of the Notification Letter.

Count I: Actavis's Filing of the ANDA Infringes the '850 Patent.

25. Plaintiffs repeat and reallege the allegations of paragraphs 1-24 as though fully set forth herein.

26. Actavis's submission of ANDA No. 79-108 to the FDA, including its Paragraph IV Certification, to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Actavis's Proposed Products prior to the expiration of the '850 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

27. Unless enjoined by this Court, Actavis, upon FDA approval of ANDA No. 79-108, will infringe the '850 patent under 35 U.S.C. § 271 by making, using, offering to sell, selling, or importing into the United States Actavis's Proposed Products.

28. Actavis had notice of the '850 patent prior to undertaking its act of infringement. Actavis's infringement of the '850 patent has been, and continues to be, willful and deliberate.

29. Plaintiffs will be substantially and irreparably damaged and harmed if Actavis's infringement of the '850 patent is not enjoined. Plaintiffs do not have an adequate remedy at law for this infringement.

Count II: Actavis's Filing of the ANDA Infringes the '656 Patent.

30. Plaintiffs repeat and reallege the allegations of paragraphs 1-24 as though fully set forth herein.

31. Actavis's submission of ANDA No. 79-108 to the FDA, including its Paragraph IV Certification, to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Actavis's Proposed Products prior to the expiration of the '656 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

32. Unless enjoined by this Court, Actavis, upon FDA approval of ANDA No. 79-108, will infringe the '656 patent under 35 U.S.C. § 271 by making, using, offering to sell, selling, or importing into the United States Actavis's Proposed Products.

33. Actavis had notice of the '656 patent, and its reexamination, prior to undertaking its act of infringement. Actavis's infringement of the '656 patent has been, and continues to be, willful and deliberate.

34. Plaintiffs will be substantially and irreparably damaged and harmed if Actavis's infringement of the '656 patent is not enjoined. Plaintiffs do not have an adequate remedy at law for this infringement.

Count III: Actavis's Filing of the ANDA Infringes the '530 Patent.

35. Plaintiffs repeat and reallege the allegations of paragraphs 1-24 as though fully set forth herein.

36. Actavis's submission of ANDA No. 79-108 to the FDA, including its Paragraph IV Certification, to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Actavis's Proposed Products prior to the expiration of the '530 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

37. Unless enjoined by this Court, Actavis, upon FDA approval of ANDA No. 79-108, will infringe the '530 patent under 35 U.S.C. § 271 by making, using, offering to sell, selling, or importing into the United States Actavis's Proposed Products.

38. Actavis had notice of the '530 patent prior to undertaking its act of infringement. Actavis's infringement of the '530 patent has been, and continues to be, willful and deliberate.

39. Plaintiffs will be substantially and irreparably damaged and harmed if Actavis's infringement of the '530 patent is not enjoined. Plaintiffs do not have an adequate remedy at law for this infringement.

Count IV: Actavis's Filing of the ANDA Infringes the 1998 '284 Patent.

40. Plaintiffs repeat and reallege the allegations of paragraphs 1-24 as though fully set forth herein.